K093205
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510(k) summary

APR - 1 2010

1. General Information

Submitter's Name: Osachi Co., LTD

Address: 9-11, Osachikohagi 2 chrome, Okaya-shi, JAPAN 394-0085

Telephone: (310) 901-7536

Contact Person: James R. Greenwood

Registration Number: 8043882

2. Device

Name:	PADCHEK ABI/PVR
Trade Name:	PADCHEK ABI/PVR
Common Name:	Pneumatic
Classification Name:	Non-invasive Blood Pressure Monitors
Product Code:	DXN
Class:	II
Regulation Number:	21 CFR 870.1130

3. Identification of Legally Marketed Devices

Name:	PADnet Lab
K Number:	K042616
Name:	VP-1000
K Number:	K013434

4. Product Overview

PADCHEK ABI/PVR performs an Ankle Brachial Index (ABI) test by measuring systolic BP at the brachial artery in each arm and systolic BP at the dorsalis pedis and/or posterior arteries at the ankles. The ABI is expressed as the ratio of ankle systolic pressure divided by the highest brachial systolic pressure. A result is obtained for each leg. A pulse wave pattern and pulse volume recording is recorded for each limb measurement. A sitting BP, pulse, pulse pressure at the brachial artery is also obtained. Results are stored in a database and can be printed at the time of point-of-care testing or later.

5. Indication For Use

The PADChek™ ABI/PVR is a non-invasive device used to assist in the detection of peripheral artery disease (PAD). Pressure measurements at the ankles (dorsalis pedis and/or posterior tibialis arteries) are compared to the highest pressure in either arm (brachial arteries) and a ABI (Ankle Brachial Index) is calculated. A Pulse Volume Recording (PVR) is simultaneously performed to determine the presence of blood flow. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

6. Device Performance

See attached data.

7. Standard compliance list

Application Standard	ISO13485:2003 IEC60601-1:2005 +A1+A2 IEC60601-1-2:2007 ISO10993-5:1999 ISO14971:2007 ANSI/AAMI SP10:2002+A1 + A2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 1 2010

Osachi Co., Ltd.
c/o Mr. James R. Greenwood
Director of Regulatory Affairs
PADTest, LLC.
801 S. Grand Ave., #1907
Los Angeles, CA 90017

Re: K093205
Trade/Device Name: PADCheck ™ ABI/PVR
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Monitors
Regulatory Class: Class II (two)
Product Code: DXN
Dated: March 5, 2010
Received: March 16, 2010

Dear Mr. Greenwood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K093205

Device Name: PADChek ABI/PVR

Indications for Use:

The PADChek ABI/PVR is a non-invasive device used to assist in the detection of peripheral artery disease (PAD). Pressure measurements at the ankles (dorsalis pedis and/or posterior tibialis arteries) are compared to the highest pressure in either arm (brachial arteries) and a ABI (Ankle Brachial Index) is calculated. A Pulse Volume Recording (PVR) is simultaneously performed to determine the presence of blood flow. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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